DEPARTMENT OF THE NAVY
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IN REPLY REFER TO
BUMEDINST 6710.66A
BUMED-04
22 May 98

BUMED INSTRUCTION 6710.66A

From: Chief, Bureau of Medicine and Surgery
To: Ships and Stations Having Medical Department Personnel

Subj: DELIVERY AND ADMINISTRATION OF OXYGEN FOR MEDICAL USE

Ref: (a) United States Pharmacopoeia, 23rd Revision of 1995

Encl: (1) Outline Procedures for Testing Oxygen Concentration
(2) FDA Anesthesia Apparatus Checkout Recommendations, 1993

1. Purpose. To provide guidelines on the delivery and administration of medical oxygen.

2. Cancellation. BUMEDINST 6710.66.

3. Background. Precautions must be taken to guard against the accidental introduction of other gases into medical oxygen systems, and to ensure anesthesia and analgesia equipment is tested for proper functioning before its use on any patient.

4. Policy

a. Oxygen Concentration and Testing. Liquid Oxygen (LOX) must contain not less than 99 percent oxygen.

(1) The gas phase of LOX must be tested. Enclosure (1) provides guidelines for testing under various circumstances. Changes are authorized to meet local conditions and available test equipment.

(a) Because of test equipment limitations, readings from commercial oxygen monitors or analyzers of 95 or greater may be considered acceptable evidence of the type and purity of gas when testing LOX in field conditions. Available field testing equipment includes commercial battery powered; polarographic, paramagnetic, or equivalent; oxygen analyzers or monitors with a full scale accuracy of within the range of plus or minus two percent.

(b) Vendor's certification that the LOX meets the requirements of reference (a) may be substituted for testing for carbon dioxide, carbon monoxide, particulate matter, and other contaminants.

(2) Molecular sieves must meet the "Oxygen 93 Percent" monograph of reference (a): between 90 and 96 percent oxygen by volume. Appropriate authorities must certify the unit capable of

producing 93 percent oxygen on delivery, before long-term storage, when placed into service, and annually. In storage, annual maintenance and operability checks must be performed.

(3) LOX test records, vendor certifications, and molecular sieve certifications must be retained for 2 years to provide an audit trail for Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), inspectors general (IG), and other authorities. These records may be destroyed after 2 years.

(4) Aviation breathing oxygen may be substituted for medical oxygen in all cases if it meets the requirements of this instruction. Humidification may be required with prolonged use.

b. Oxygen Administration

(1) When a specific concentration is prescribed, oxygen must be monitored at the point of administration. Patient records shall indicate the flow rate and concentration.

(2) All anesthesia and analgesia equipment shall be tested at time of delivery of new equipment, repair of existing equipment, and before each patient use. Enclosure (2) provides a recommended checklist before use. With appropriate peer review, enclosure (2) may be changed to meet local conditions, such as equipment design, technology changes, and variations in clinical practice. Testing shall be documented in the equipment maintenance record, or in the patient medical record, as appropriate.

c. Emergency Plan. Each activity with a central oxygen supply system shall maintain a written emergency plan to deal with a system malfunction. The plan shall describe any alarms installed, the actions to be taken when an alarm activates, and shall identify those clinical areas that will need an alternate oxygen supply until the central oxygen supply system is operating properly within the required pressures.

5. Action. Commanders, commanding officers, officers in charge, or other proper authority shall:

a. Appoint, in writing, individuals to test LOX deliveries, document such testing, and to accept or reject LOX deliveries. If necessary, appoint individuals to certify that molecular sieve equipment meets the "Oxygen 93 percent" monograph in reference (a).

b. Establish procedures to ensure that anesthesia and analgesia equipment are properly tested before each use on any patient, and all testing is documented in the equipment

maintenance record, or in the patient medical record, as appropriate. Review enclosure (2) and document this review in a "Policy and Procedure Manual" or similar publication.

c. Maintain a central oxygen supply system malfunction plan for any installed central oxygen supply system.

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Available at:
http://support1.med.navy.mil/bumed/instruct/external/external.htm

OUTLINE PROCEDURES FOR TESTING OXYGEN CONCENTRATION

The following is a generic procedure to test oxygen (O_2) concentration. Commands may change these procedures to fit different makes and models of test equipment and to meet unique local requirements.

1. General Equipment Requirements

a. Battery powered O_2 analyzer.

b. Test gas reservoir. An O_2 nebulizer bottle with a 15-22 mm outlet is preferred. Heaters are not required.

c. Back flow compensated O_2 flow meter (two each).

d. O_2 regulator. One stage if testing a 50 pounds per square inch gauge (psig) source, two stage if source is greater that 50 psig.

e. Calibration gas or known 100 percent O_2 source.

f. Low pressure connecting hose, O_2 diameter indexed safety system (DISS fittings) (two each).

g. O_2 cylinder truck or cart. (One for each cylinder).

h. Grounding cable, 15 to 20 feet with extra large alligator type clips on each end.

2. Safety Precautions

a. Always work in a well ventilated space away from open flames or sparks. Ventilation avoids the buildup of O_2 that is released by leaks or during the testing process.

b. Use only tools designed for use with O_2 delivery systems. Tools must be nonsparking, oil and contamination free, and reserved for use with O_2 only.

c. Area must be clean and free of combustibles, especially oil and other petroleum products. In an O_2 enriched atmosphere, normally noncombustible materiel will burn easily.

d. Follow standard operating procedures for use and storage of compressed gas cylinders.

e. Always assemble and test O_2 administration equipment away from patient care areas.

3. Assemble Reference or Calibration Gas Source

a. Secure each cylinder to a cylinder truck or cart.

b. Open the cylinder valve slightly to clear any foreign matter. Face the opening away from yourself and others. The valve will clear within 1 second and should then be closed.

c. Fit an O_2 regulator to reference or calibration gas cylinder and tighten the connection with a proper wrench.

d. Attach a pressure compensated flow meter to the low pressure outlet of the O_2 regulator. Tighten the flow meter connection with a proper wrench.

e. Attach an O_2 nebulizer bottle to the outlet of the flow meter and tighten hand-tight.

f. With a flow valve opened slightly, slowly open the cylinder valve to fully open. The meter should register flow and the flow should be heard. Close the flow meter valve so the flow stops. Do not over tighten the flow meter or use force to stop the flow. Over tightening this valve will damage the flow meter. If the flow does not stop with finger tight pressure, turn the flow meter in to medical repair and use another flow meter.

4. Calibrate the Oxygen Analyzer

a. Review the manufacturer's calibration instructions.

b. Open the reference or calibration gas flow meter valve until a flow of 10-12 liters per minute through the nebulizer is indicated. Allow the nebulizer jar to be flushed with O_2 for at least 15 seconds before sampling.

c. When the manufacturer's instruction require a sample of 99 or 100 percent source, place the analyzer probe in or on the nebulizer jar and calibrate the high-point of the instrument.

d. Low-point calibration of the analyzer is performed using ambient air (21 percent oxygen). Ensure you are well clear (20-25 feet) of other O_2 sources while performing the low-point calibration.

5. Assemble the Test Gas Assembly and Test the Concentration. This procedure will vary with the source of the gas to be tested.

a. LOX Delivery Truck With a 50 psig Regulator

(1) Attach a nebulizer jar to the outlet of a flow meter. Tighten connection hand-tight.

(2) Attach a low-pressure O_2 hose to the inlet of the flow meter. Tighten connection hand-tight.

(3) Have the delivery truck driver attach a ground cable from the delivery truck to the metal connection on the test gas flow meter. This cable will dissipate any static charges and reduce the hazard of sparks in an O_2 enriched atmosphere.

(4) Have the delivery truck driver attach the opposite end of the low-pressure O_2 outlet to the regulated 50 psig outlet on the truck.

(5) Sample the head gas contents of the delivery truck.

(a) Open the flow meter control valve slightly.

(b) Ask the driver to open the truck's sample port.

(c) Adjust the flow meter for a flow rate of 10-12 liters per minute and flush the test gas nebulizer jar for at least 15 seconds. Test the contents of the nebulizer jar as specified by the manufacturer and record the results.

(6) Have the driver close the sample port valve and allow the pressure to bleed off the test circuit through the flow meter. When the flow returns to zero, request the driver remove the low-pressure hose from the truck. Wait 30 seconds to allow dissipation of gases from the area, then have the driver remove the grounding cable.

(7) Remove all test equipment from the area. Record the liquid level of the LOX tank before the filling operation. Stand well clear of the LOX tank and truck during the filling operation.

(8) Observe as the driver connects the LOX tank and truck, making sure the fittings connect easily, without the use of oversized wrenches.

(9) Record the liquid level of the LOX tank after the driver has disconnected the transfer hoses.

b. LOX Delivery Truck Without a 50 psig Regulator. Procedure is similar to paragraph 6a, except have the driver place a single stage O_2 regulator on the sample port. Connect the distal end of the low-pressure O_2 hose to the output of the regulator.

c. High Pressure Oxygen Cylinders

(1) Ensure O_2 analyzer has been calibrated with a known 100 percent O_2 source. Assemble an O_2 test circuit with the following parts: 50 psig O_2 regulator, pressure compensated O_2 flow meter, and an O_2 nebulizer bottle.

(2) Secure all cylinders in a cylinder truck or cart, or chain in a compressed gas cylinder rack.

(3) Remove the safety cap from the cylinder. Clear the cylinder valve by briefly opening the valve for 1 second.

(4) Attach O_2 test circuit to cylinder to be tested and tighten the connection with a proper wrench.

(5) With the flow meter valve opened slightly, open the cylinder valve slowly. Adjust the flow meter to 10-12 liters per minute flow and flush the test gas nebulizer bottle for at least 15 seconds. Sample the nebulizer bottle contents as specified by the O_2 analyzer manufacturer and record the results.

(6) Close the cylinder valve and allow the pressure to bleed off the test circuit through the flow meter. When the flow returns to zero, remove the O_2 test circuit from the cylinder with an appropriate wrench and reinstall the cylinder safety cap.

d. Molecular Sieves

(1) Ensure O_2 analyzer has been calibrated with a known 100 percent O_2 source. As appropriate, assemble an O_2 test circuit with the following parts: 50 psig O_2 regulator (if concentrator outlet pressure is higher than 50 psig), pressure compensated O_2 flow meter, and an O_2 nebulizer bottle.

(2) Clear the O_2 concentrator outlet by briefly opening the control valve for 1 second.

(3) Attach O_2 test circuit to the outlet and tighten the connection with a proper wrench.

(4) With the flow meter valve opened slightly, open the cylinder valve slowly. Adjust the flow meter to 10-12 liters per minute flow and flush the test gas nebulizer bottle for at least 15 seconds. Sample the nebulizer bottle contents as specified by the O_2 analyzer manufacturer and record the results.

(5) Close the outlet control valve and allow the pressure to bleed off the test circuit through the flow meter. When the flow returns to zero, remove the O_2 test circuit from the concentrator with a proper wrench.

FDA ANESTHESIA APPARATUS CHECKOUT RECOMMENDATIONS, 1993

This checkout, or a reasonable equivalent, should be conducted before administration of anesthesia. These recommendations are only valid for an anesthesia system that conforms to current and relevant standards and includes an ascending bellows ventilator and at least the following monitors: capnograph, pulse oximeter, oxygen analyzer, respiratory volume monitor (spirometer), and breathing system pressure monitor with high and low pressure alarms. This is a guideline which users are encouraged to modify to accommodate differences in equipment design and variations in local clinical practice. Such local modifications should have appropriate peer review. Users should refer to the operator's manual for the manufacturer's specific procedures and precautions, especially the manufacturer's low pressure leak test (step #5).

Emergency Ventilation Equipment

*1. Verify Backup Ventilation Equipment is Available and Functioning.

High Pressure System

*2. Check Oxygen Cylinder Supply
   a. Open O_2 cylinder and verify at least half full (about 1,000 psi).
   b. Close cylinder.

*3. Check Central Pipeline Supplies. Check that hoses are connected and pipeline gauges read about 50 psi.

Low Pressure System

*4. Check Initial Status of Low Pressure System
   a. Close flow control valves and turn vaporizers off.
   b. Check fill level and tighten vaporizers' filler caps.

*5. Perform Lead Check of Machine Low Pressure System
   a. Verify the machine master switch and flow control valves are off.
   b. Attach "suction bulb" to common (fresh) gas outlet.
   c. Squeeze bulb repeatedly until fully collapsed.
   d. Verify bulb stays fully collapsed for at least 10 seconds.
   e. Open one vaporizer at a time and repeat "c" and "d" above.
   f. Remove suction bulb, and reconnect fresh gas hose.

*6. Turn On Machine Master Switch and all other necessary equipment.

*7. Test Flow Meters
   a. Adjust flow of all gases through their full range, checking for smooth operation of floats and undamaged flow tubes.
   b. Attempt to create a hypoxic O_2/N_2O mixture and verify correct changes in flow or alarm.

Scavenging System

*8. Adjust and Check Scavenging System
   a. Ensure proper connections between the scavenging system and both APL (pop-off) valve and ventilator relief valve.
   b. Adjust waste gas vacuum (if possible).
   c. Fully open APL valve and occlude Y-piece.
   d. With minimum O_2 flow, allow scavenger reservoir bag to collapse completely and verify that absorber pressure gauge reads about zero.
   e. With the O_2 flush activated, allow the scavenger reservoir bag to distend fully, and then verify that absorber gauge reads < 10 cm H_2O.

Breathing System

*9. Calibrate O_2 Monitor
   a. Ensure monitor reads 21 percent in room air.
   b. Verify low O_2 alarm is enabled and functioning.
   c. Reinstall sensor in circuit and flush breathing system with O_2.
   d. Verify that monitor now reads greater than 90 percent.

10. Check Initial Status of Breathing System
   a. Set selector switch to "Bag" mode.
   b. Check that breathing circuit is complete, undamaged, and unobstructed.
   c. Verify that CO_2 absorbent is adequate.
   d. Install breathing circuit accessory equipment (e.g., humidifier, PEEP valve) to be used during the case.

11. Perform Leak Check of the Breathing System
   a. Set all gas flows to zero (or minimum).
   b. Close APL (pop-off) valve and occlude Y-piece.
   c. Pressurize breathing system to about 30 cm H_2O with O_2 flush.
   d. Ensure that pressure remains fixed for at least 10 seconds.
   e. Open APL (pop-off) valve and ensure that pressure decreases.

Manual and Automatic Ventilation Systems

12. Test Ventilation Systems and Unidirectional Valves
    a. Place a second breathing bag on Y-piece.
    b. Set appropriate ventilator parameters for next patient.
    c. Switch to automatic ventilation (Ventilator) mode.
    d. Turn ventilator ON and fill bellows and breathing bag with O_2 flush.
    e. Set O_2 flow to minimum, other gas flows to zero.
    f. Verify that during inspiration bellows delivers appropriate tidal volume and that during expiration bellows fills completely.
    g. Set fresh gas flow to about 5 L/min.
    h. Verify that the ventilator bellows and simulated lungs fill and empty appropriately without sustained pressure at end expiration.
    i. Check for proper action of unidirectional valves.
    j. Exercise breathing circuit accessories to ensure proper function.
    k. Turn ventilator OFF and switch to manual ventilation (Bag/APL) mode.
    l. Ventilate manually and assure inflation and deflation of artificial lungs and appropriate feel of system resistance and compliance.
    m. Remove second breathing bag from Y-piece.

Monitors

13. Check, Calibrate, and/or Set Alarm Limits of all Monitors
    a. Capnometer
    b. Oxygen Analyzer
    c. Pulse Oximeter
    d. Respiratory Volume Monitor (Spirometer)
    e. Pressure Monitor with High and Low Airway Alarms

14. Check Final Status of Machine
    a. Vaporizers off
    b. APL valve open
    c. Selector switch to "Bag"
    d. All flow meters to zero
    e. Patient suction level adequate
    f. Breathing system ready to use

* *If an anesthesia provider uses the same machine in successive cases, these steps need not be repeated or may be abbreviated after the initial checkout.*